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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/816,611 | 04/02/2004 | Terry William Balko | 62,381A | 9814 |

25212 7590 02/09/2006

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EXAMINER

QAZI, SABIHA NAIM

| | |
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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/816,611 | BALKO ET AL. | |
| | Examiner | Art Unit | |
| | Sabiha Qazi | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 6 is/are rejected.
- 7) ☐ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Final Office Action

Acknowledgement is made of the response filed on 01/17/2006. Claims 1-6 are pending.

Claim 4 is objected. No claim is allowed.

Response to Remarks

- Applicant's arguments were fully considered but were not found persuasive therefore the rejection is maintained for the same reasons as set forth in our previous office action.
- In order to advance the prosecution Applicant may consider calling the Examiner to discuss the issues surrounding this application.
- Applicant argues that "the compounds in question where -NR1R2 taken together can be 5- or 6-membered saturated or unsaturated ring are not radically different from when R1 and R2 are independently C1-C6 alkyl or C3-C6 alkenyl" (2nd para of remarks on page 4). Examiner respectfully disagrees because chemically the compounds containing saturated or unsaturated rings are very different from the compounds, which do not have these rings. Also Applicants themselves demonstrated in various declarations that even a minor change of substitution such as F vs. Cl gives unexpected results.
- Applicant's reference to two US Patents has been considered however; every case is examined at its merits.
- Claims drawn to a genus where R1 and R2 do not form a saturated or unsaturated and hetero ring are allowable. The declaration filed by Mr. Paul R. Schmitzer clearly shows that compound containing F or H at 5-position of pyridine is better than compounds containing Cl.
- Single Species:

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A single species is seldom, if ever, sufficient to support a generic claim. In re Shokal, 242 F.2d 771, 113 U.S.P.Q. 283, 285 (C.C.P.A. 1957). See also, In re Grimme, 274 F.2d 949, 124 U.S.P.Q. 499, 501 (C.C.P.A. 1960) (the naming of a member of a genus or subgenus is not a proper basis for claiming the whole group).

Objective evidence of nonobviousness must be commensurate in scope with the scope of the claims. In re Tiffin, 171 USPQ 294. A showing limited to a single species can hardly be considered probative of the invention's nonobviousness in view of the breadth of the claims.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-6 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds containing non hetero groups at 4-position of

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the pyridine ring does not reasonably provide enablement for the compounds and methods when W represents 5 or 6-membered aromatic ring containing one or more heteroatoms, viz., N, O, or S; these hetero aromatic rings may be fused to other aromatic systems. See lines 30-32 on page 6 and lines 1-13 on page 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The amount of direction or guidance presented: There is no guidance in the disclosure on how to use the invention successfully for any heterocyclic compounds as claimed. Claims are broad. The method of controlling undesired vegetation cannot be predicted.

See In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule:

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"It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)).

The presence or absence of working examples: There are no working examples and/or data to support the claimed heterocyclic groups as substituents at 4-position in claimed invention.

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The quantity of experimentation necessary: Since there are no working examples, no

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data, and no guidance presented in the disclosure for heterocyclic substituted compounds at 4-position, one skilled in the art at the time of invention would have to go through undue experimentation to make and/or use the presently claimed invention.

Claim 4 is objected for depending on a rejected claim. This claim will be allowed when written separately.

DECLARATION

The declaration filed by Mr. Paul R. Schmitzer clearly shows that compound containing F or H at 5-position of pyridine is better than compounds containing Cl. On the basis of unexpected results rejection over BE 788,756 was withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan, Sreeni (acting) can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saturday, February 04, 2006



SABIHA QAZI, PH.D.
PRIMARY EXAMINER